



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR        | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------------|---------------------|------------------|
| 09/787,508      | 05/10/2001  | Roland Cherif Cherif Cheikh | BET01/0233          | 2278             |

466 7590 08/10/2005

YOUNG & THOMPSON  
745 SOUTH 23RD STREET  
2ND FLOOR  
ARLINGTON, VA 22202

EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 08/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/787,508

Applicant(s)

CHERIF CHEIKH ET AL.

Examiner

Matthew F. DeSanto

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 5/17/05.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 45-47 and 49-89 is/are pending in the application.
- 4a) Of the above claim(s) 56 and 58-86 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-47, 49-55, 57 and 87-89 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

The 112 rejection has been withdrawn because of the amendment to the claims.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 45, 46, 47, 49, 50, 51, 52, 87, 88 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamashita (55-7352).

Yamashita discloses a syringe with a reservoir, a piston, a base, needle, and wherein the needle is fastened to the reservoir by direct application of the element forming the reservoir against the base by a support or casing (13) which houses said element forming the reservoir. (Figures 1, 4 and 5 and entire reference).

As to claim 45, wherein said element forming the reservoir provides mechanical resistance of the syringe. (Figures 1, 4, 5 and entire reference).

2. Claims 45, 47, 49, 51, 52, and 87-89 are rejected under 35 U.S.C. 102(b) as being anticipated by W. Roos (USPN 2,537,550).

W. Roos discloses a syringe with a hollow element (d) including a reservoir, a piston, a base, needle (b), and wherein the needle is fastened to the reservoir by direct application of the element forming the reservoir against the base by a support or casing (a) which houses said element forming the reservoir (Figures 1, 2 and entire reference).

3. Claim 45-47, 49 - 52, and 87-89 are rejected under 35 U.S.C. 102(e) as being anticipated by DeChellis et al. (USPN 4,921,486)

4. DeChellis et al. discloses a syringe with a reservoir, a piston, a base, needle, and wherein the needle is fastened to the reservoir by direct application of the element forming the reservoir against the base by a support or casing which houses said element forming the reservoir. The needle is in a fixed engagement in figure 1 and 2. (Figures 1, 2 and entire reference)

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 53-55, and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamashita as applied to the claims above, and further in view of Higashikawa (USPN 5704918).

With regard to claims 53-55, Yamashita meets the claim limitations as described above but fails to include the claimed dimensions. At the time of the invention, it would have been obvious to construct the device from the claimed dimensions since the

Art Unit: 3763

Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

With regard to claim 57;

Yamashita disclosed the claimed invention but fails to disclose wherein the tubular reservoir has more than two tubes.

Higashikawa disclosed an adjustable dispensing syringe with an outer cast, and two inner tubes that form inside the reservoir.

At the time of the invention it would have been obvious for a person of ordinary skill in the art to combine the disclosed invention of Yamashita with the teachings of Higashikawa because it is well known in the art to use two tubes when combining different agents being injected into the body, especially when one agent is a liquid and the other agent is a solid material.

### ***Response to Arguments***

7. Applicant's arguments filed 5/17/05 have been fully considered and some are persuasive and some are not persuasive.

8. Chanoch et al., doesn't directly disclose the needle coming into direct contact with the piston and thus the 102 rejection has been withdrawn.

9. The applicant argues that Yamashita (JP-55-73352) does not have substantially zero clearance and that the casing member does not provide axially force to strengthen the hollow element. With regards to the zero clearance, the applicant has used the term

Art Unit: 3763

"substantially" which broadens the limitation of zero clearance. The term substantially does not recite and space or given any dimensions, and therefore the term can be interpreted broadly, which is how it is in this case. Yamashita shows the substantially zero clearance in the Figures. Yamashita is "almost contacting" the inner walls of the casing and therefore, Yamashita teaches this limitation. With regards to the casing member not providing support, this is the reason for the thread, to provide support and strength to the syringe and the whole apparatus. The examiner would also like to note that this language is functional language and the casing member has the capability to perform the function claimed, since the structure is the same. According to the MPEP there must be a structural difference between the prior art and the claimed invention in order to receive a patent (MPEP 2114). The applicant is arguing functional language and fails to disclose the structural difference between the prior art and the applicant's invention. With regards to the reservoir prefilled with a semi-solid preparation, it is well known that syringe can be prefilled with various preparations, as seen in the other prior art. The applicant is relying on the abstract and not the entire disclosed invention, which further supports the rejection over the claimed invention.

10. With regards to Roos, the applicant argues that element b cannot be a needle and that the "needle" is not fastened to the hollow element of the casing. The examiner disagrees with both interpretations of the prior art. Element b is pointed and slender, thus reads on the definition of a needle. A needle doesn't need to be sharp. The examiner also disagrees with the needle being threaded to the hollow element by the casing, but not fastened. According to the dictionary definition of fastened, it would be

interpreted as securing an object to another, which is the purpose of the threaded engagement of Roos.

11. With regards to Dechallis the examiner disagrees with the applicant's interpretation of this reference. The needle is fixedly engaged prior to injection and during injection. Therefore, if the syringe is never or only partially used the needle would still be fixedly engaged between the reservoir and the housing.

### ***Conclusion***

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone

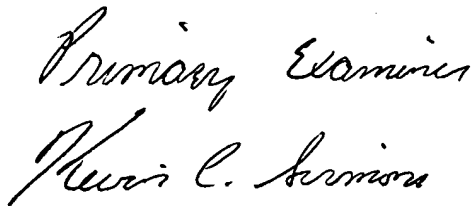
Art Unit: 3763

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto  
Art Unit 3763  
August 8, 2005



Primary Examiner  
Kevin C. Harrison